



United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7508C)

September 24, 2003

Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision (TRED) for Lactofen



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is the Environmental Protection Agency's (hereafter referred to as EPA or the Agency) "Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision for Lactofen," which was approved on September 24, 2003. This document is also known as a Tolerance Reassessment Decision, or TRED. A Notice of Availability of this tolerance reassessment decision and an announcement of a 30-day public comment period will be published in the *Federal Register* shortly.

Regulatory Determination

The Federal Food, Drug and Cosmetic Act (FFDCA), as amended by FQPA, requires EPA to reassess all the tolerances for registered chemicals in effect on or before the enactment of the FQPA on August 3, 1996. In reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. Once a safety finding has been made that aggregate risks are not of concern, the tolerances are considered reassessed. Existing tolerances associated with lactofen must be reassessed in accordance with FFDCA, as amended by FQPA. Ecological and occupational assessments were originally conducted when lactofen was first registered. Therefore, no further ecological or occupational assessments are being conducted as part of this TRED.

The Agency has evaluated the dietary risk associated with all currently registered uses of lactofen and has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to lactofen when considering dietary exposure and all other non-occupational sources of pesticide exposure for which there is reliable information. Therefore, no mitigation measures are needed, and the two (2) tolerances established for residues of lactofen in/on raw agricultural commodities are now considered reassessed as safe under section 408(q) of the FFDCA.

As part of the TRED, the Agency also considered petitions for establishment of new food uses and associated tolerances of lactofen on cotton and peanuts. To evaluate the tolerance petition and determine if new tolerances should be established, EPA considered all of the criteria described above to

ensure that the FQPA safety standard was met. For the proposed new food uses of lactofen on cotton and peanuts, the Agency has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to lactofen. However, because the TRED pertains only to the existing tolerances, the establishment of the new food uses and associated tolerances is outside the scope of this TRED and will be determined by a separate decision.

The Agency's human health findings for the pesticide lactofen are summarized in the enclosed chemical overview of the risk assessments. For further details, please refer to the enclosed list of risk assessments and other technical documents pertaining to the lactofen TRED, which are available on the Internet at <http://www.epa.gov/e-dockets> and in the public docket for viewing.

FQPA Assessment

FQPA requires that EPA consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The Agency considers other substances because low-level exposures to multiple chemical substances that cause a common toxic effect by a common mechanism could lead to the same adverse health effect, as would a higher level of exposure to any of the other substances individually.

Lactofen belongs to the diphenyl ether class of chemicals. The Agency has not yet determined whether lactofen and the other diphenyl ether herbicides exhibit a common mechanism of toxicity. Therefore, the Agency defers any cumulative risk assessment to a later date. For the purposes of tolerance reassessment for lactofen, EPA is assuming no common mechanism with other compounds. Therefore, a cumulative assessment was not conducted for this TRED. However, because lactofen is expected to degrade to acifluorfen in the environment, EPA did consider the contribution of acifluorfen from use of sodium acifluorfen as an herbicide and as an environmental degradate of lactofen in the aggregate assessment.

Based on currently available data, lactofen does not appear to be an endocrine disruptor. However, when the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disruptor Screening Program have been developed, lactofen may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

Tolerance Summary

Tolerances for lactofen in or on raw agricultural commodities for plants are currently established for the combined residues of lactofen and its associated metabolites containing the diphenyl ether linkage, but will be revised to include only lactofen *per se*. The two existing tolerances for lactofen have been reassessed and will be lowered from 0.05 ppm to 0.01 ppm. There are currently no tolerances for lactofen in processed commodities or animal commodities, and the available residue data indicate that tolerances for these commodities are not necessary. No maximum residue limits (MRLs) for lactofen have been established or proposed by Codex. Therefore, there are no international compatibility issues with respect to U.S. tolerances. A summary of the lactofen tolerance reassessment and recommended modifications in commodity definitions are presented in Table 1.

Table 1. Tolerance Reassessment Summary for Lactofen.

Commodity	Established Tolerance (ppm) ^a	Reassessed Tolerance (ppm) ^b	Comment [Correct Commodity Definition]
Tolerances listed under 40 CFR §180.432(a):			
Beans, snap	0.05	0.01	<i>Beans, snap, succulent (excluding Limas)</i>
Soybean	0.05	0.01	<i>Soybean, seed</i>

^a Expressed in terms of lactofen and its metabolites containing the diphenyl ether linkage

^b Expressed in terms of lactofen *per se*

As previously mentioned, the Agency has considered petitions for new food uses on cotton and peanuts in the TRED, but the decision to establish new tolerances will be made separately by the Agency. The residue chemistry data for cotton and peanuts has been reviewed and included in the dietary risk assessment for this TRED.

Uses Subject to TRED and Label Amendments

The food and feed uses and associated use patterns subject to this TRED are listed in Table 2. The lactofen labels must conform with the use patterns and use limitations listed in Table 2, which follows. Table 2 does not include the forestry use, as this use is not expected to impact the dietary exposure of any population subgroup and, therefore, is not included in this assessment.

Additional Generic Data Requirements

As mentioned in the attached *Overview of Lactofen FQPA Risk Assessment for Tolerance Reassessment*, several confirmatory data requirements have been identified for lactofen. These are listed in Table 3 and will be included in a Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)(2)(B) data call in (DCI) to be sent under separate cover. These data are not expected to change the regulatory conclusions for lactofen described in this document.

This document summarizes the Agency's decision on the tolerance reassessment for lactofen. Please contact Christina Scheltema of my staff with any questions regarding this decision. She may be reached by phone at (703)308-2201 or by e-mail at scheltema.christina@epa.gov.

Sincerely,

Betty Shackleford, Acting Director
Special Review and
Reregistration Division

Enclosures: *Technical Support Documents for the Lactofen TRED*
Overview of Lactofen FQPA Risk Assessment for Tolerance Reassessment

Table 2. Food/Feed Use Patterns Subject to Tolerance Reassessment for Lactofen (PC Code 128888).

Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Max. Single Application Rate (lb ai/A)	Max. # Apps./season	Minimum Retreatment Interval (Days)	Use Limitations
Cotton (Non-Food Use)					
Postemergence directed ground applications to plants at least 6 inches in height Ground equipment	2 lb/gal EC [59639-34]	0.4	2	None	A 70-day PHI is specified. A 12-hour REI is specified. Applications may include crop oil concentrate at up to 2 pt/A or a non-ionic surfactant at 2 pt/100 gal of spray solution. For banded applications, the application rate and broadcast volume should be reduced in proportion to the area treated. Do not apply through any type of irrigation system. Do not graze animals on forage or stubble or utilize hay or straw for animal feed or bedding.
Soybeans					
Broadcast and banded, pre- and postemergence applications Ground or aerial equipment	2 lb/gal EC [59639-34]	0.3 - preemergence 0.2 - postemergence	2	None	A 12-hour REI is specified. Do not apply within 45 days of harvest or after growth stage R6 (full seed); 90-day PHI is specified in NY. Do not graze animals on forage or stubble or utilize hay or straw for animal feed or bedding. Do not apply more than 0.3 lb ai/A preemergence per season and more than a total of 0.4 lb ai/A/season (0.2 lb ai/A/season in NY) Do not apply through any type of irrigation system. Minimum application volumes of 5 and 10 gal/A are specified for aerial and ground applications, respectively. For banded applications, the application rate and broadcast volume should be reduced in proportion to the area treated. Applications may include 0.125-2% (v/v) of a crop oil concentrate or 0.25% of a non-ionic surfactant.

Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Max. Single Application Rate (lb ai/A)	Max. # Apps./season	Minimum Retreatment Interval (Days)	Use Limitations
Soybeans (<i>continued</i>)					
Postemergence broadcast or banded applications Ground equipment	2.4 lb/gal EC [59639-92]	0.13	2	None	A 60-day PHI is specified. Do not graze animals on forage or stubble or utilize hay or straw for animal feed or bedding. A minimum application volume of 15 gal/A is specified. Applications may include 1-2 pts./A of crop oil concentrate or methylated seed oil. Do not apply by air. Do not rotate to crops other than soybeans or field corn within 30 days of the last application. Do not rotate to small grains for at least 120 days after the last application.
Snap beans (in OR and TN only)					
Preemergence broadcast application within 48 hours of planting. Ground equipment	2 lb/gal EC [59639-34]	0.22 - OR 0.25 - TN	1	Not Applicable	Restricted to use in OR and TN. A 55-day PHI is specified. Apply no later than 48 hours after planting. Do not apply to soils with high sand contents (sandy loams, loamy sands, and gravelly sandy loams)

Table 3. Confirmatory Data Requirements for Lactofen

OPPTS Guideline Number	Guideline Name	Compound(s) Which Must be Tested	Comment/Rationale
870.3700	Prenatal developmental toxicity study in rabbits	Technical	Data gap
860.1850	Confined Rotational Crop Study	Pure active ingredient radiolabeled	Required because confined rotational crop study in root crops indicated minimal uptake of radioactivity in carrots and radishes planted after lactofen application.
830.7050	UV/Visible Absorption	Technical (76% ai) EPA Reg. No. 59639-94 Formulation Intermediate (60% ai) EPA Reg. No. 59639-70	New Guideline Requirement

**Technical Support Documents
for the Lactofen TRED**

1. Michael Metzger (USEPA/OPPTS/OPP/HED). Lactofen. Revisions to HED Tolerance Reassessment Risk Assessment. August 12, 2003.
2. Christine Olinger (USEPA/OPPTS/OPP/HED). Lactofen: Preliminary Human Health Risk Assessment for Tolerance Reassessment Incorporating Revised Cancer Unit Risks. October 12, 2000.
3. Robert Fricke (USEPA/OPPTS/OPP/HED). Lactofen: Report of the Mechanism of Toxicity Assessment Review Committee. March 12, 2001.
4. (USEPA/OPPTS/OPP/HED). Cancer Assessment Document: Evaluation of Carcinogenic Potential of Lactofen (Second Review). Cancer Assessment Review Committee. May 21, 2002.
5. James Wolf (USEPA/OPPTS/OPP/EFED). Drinking Water Exposure Assessment for Lactofen Updated for Prospective Ground Water (PGW) Monitoring Study. January 21, 2003.
6. James Wolf (USEPA/OPPTS/OPP/EFED). EFED Review of Lactofen Small Scale Prospective Ground Water Monitoring Study 166-1. February 26, 2003.
7. Kit Farwell (USEPA/OPPTS/OPP/HED). Sodium Acifluorfen. Revision to the HED Chapter for the Reregistration Eligibility Document. July 14, 2003.
8. Elizabeth Mendez (USEPA/OPPTS/OPP/HED). Lactofen: Toxicology Evaluation. March 2, 2000.
9. Brenda Tarplee (USEPA/OPPTS/OPP/EFED). Lactofen - Report of the FQPA Safety Factor Committee. March 25, 2000
10. George Keitt. (USEPA/OPPTS/OPP/BEAD). RED Use Profile Report for Lactofen. April 7, 1998.